MARK T. JANSEN (SBN 114896)
mjansen@crowell.com
PILAR R. STILLWATER (SBN 260467)
pstillwater@crowell.com
GALEN P. SALLOMI (SBN 306743)
gsallomi@crowell.com
CROWELL & MORING LLP
275 Battery Street, 23rd Floor
San Francisco, California 94111
Telephone: 415.986.2800
Facsimile: 415.986.2827

KATHRYN L. CLUNE (pro hac vice application to be filed)
kclune@crowell.com
ALI H.K. TEHRANI (pro hac vice application to be filed)
atehrani@crowell.com
CROWELL & MORING LLP
1001 Pennsylvania Ave, NW
Washington, DC 20004
Telephone: 202.624.2705
Facsimile: 202.628.5116

Attorneys for Plaintiff
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, a California Corporation,

Plaintiff,

v.

ATRICURE, INC., a Delaware Corporation,

Defendant.

Case No. 3:16-cv-6506

COMPLAINT FOR PATENT INFRINGEMENT

JURY TRIAL DEMANDED

Plaintiff The Regents of the University of California ("The Regents" or "Plaintiff"), by and through its undersigned counsel, complains and alleges against AtriCure, Inc. ("Defendant" or "AtriCure"), as follows:

BACKGROUND AND NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, and specifically § 271, for Defendant's infringement of The Regents' patents covering the now-standard and universally utilized method of treating atrial fibrillation.

2. Atrial fibrillation (also referred to as "AFib" or "AF") is the most common type of abnormal heart rhythm. AFib can be an extremely serious condition that severely limits physical activities and significantly increases the risk of other serious heart diseases, stroke, and death. It is estimated that five million people in the United States suffer from AFib currently, and that this number will reach up to 12 million people by 2050. Approximately 450,000 new cases of AFib are diagnosed in the U.S. alone each year. These figures are expected to increase as the population ages.

3. Atrial fibrillation is caused by irregular electrical activity that is triggered typically from specific locations in the pulmonary veins, or near the entrance of the pulmonary veins in the left atrium of the heart. Absent appropriate treatment, the erratic electrical pulses travel from the pulmonary vein into the left atrium, wherein they trigger the onset of AFib, which causes erratic heart muscle contractions and decreases the effectiveness of the heart's ability to pump blood through the patient's body.

4. Medical researchers spent decades attempting to develop safe and effective non-pharmacologic treatment methods. Dr. Michael Lesh MD, a professor of medicine and a cardiac electrophysiologist at the University of California, San Francisco (or "UCSF"), finally solved the problem by inventing the first safe and reliable minimally invasive method of treating AFib.

5. The treatment method invented by Dr. Lesh (the "Patented Method") involves the formation of a circumferential conduction block at a location where a pulmonary vein extends from the heart's left atrium. The resulting conduction block is intended to block electrical pulses originating within or near the pulmonary vein(s) and to prevent them from entering the left atrium and triggering atrial fibrillation. Dr. Lesh filed several related patent

applications, prosecuted by and on behalf of The Regents, directed to the Patented Method, including the two patents asserted in this action. All of these patents are duly assigned to The Regents (collectively, "The Regents' Patents").

6. AtriCure and the relevant medical community have, at all relevant times, consistently referred to the Patented Method as "pulmonary vein isolation," "PVI," "circumferential PVI," "circumferential conduction block," "electrical isolation of the pulmonary veins," and other, similar, terms.

7. The Patented Method has proven highly successful in treating atrial fibrillation. During the early 2000s, relevant medical professionals, such as doctors, cardiologists, cardiac electrophysiologists, and cardiothoracic surgeons, universally adopted the Patented Method as the accepted method of treating AFib, either alone, or in combination with other therapy.

8. Defendant AtriCure has, at all relevant times, been one of the major manufacturers of surgical instruments and related equipment used to treat AFib. AtriCure manufactures, markets, and sells a range of medical devices and related equipment (collectively, "AtriCure Devices") that are used to perform the Patented Method to treat AFib.

9. AtriCure has, at all relevant times, had knowledge of The Regents' Patents, including the two patents asserted in this action. AtriCure is also well aware of the widespread use of AtriCure Devices to perform the Patented Method. Moreover, AtriCure has actively induced, and continues to induce, medical professionals to use AtriCure Devices specifically to practice the Patented Method. In addition, certain of the AtriCure Devices have no substantial use other than to perform the Patented Method, making AtriCure liable for contributory patent infringement in its marketing and sale of those devices.

THE PARTIES

10. Plaintiff The Regents is a California corporation, with a principal place of business located in Oakland, California. The Regents makes up the governing board of the University of California. The Regents maintains a principal, and world-renowned, medical research facility, the University of California, San Francisco, in the City and County of San Francisco. All actions are done in The Regents' name, including owning property such as

patents and other intellectual property and entering into contracts.

11. Defendant AtriCure is a Delaware corporation with corporate headquarters in West Chester, Ohio. AtriCure has at least one office and research facility located in this District.

JURISDICTION AND VENUE

12. This court has original and exclusive subject matter jurisdiction over this controversy pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over AtriCure because AtriCure's contacts with the State of California are significant and pervasive, and because AtriCure's contacts with California, as described in this Complaint, directly give rise to this dispute. AtriCure has at least one research facility and office in California, located in this District in San Ramon, Alameda County.

14. AtriCure has conducted substantial business with individuals, hospitals, and other medical institutions and facilities throughout the State of California, including in this District, and it actively promotes and sells its medical devices and equipment, including the AtriCure Devices that are the subject of this action, throughout California. In doing so, AtriCure regularly transacts business throughout the state, and in this District, in violation of the Asserted Patents, as alleged in this Complaint. Accordingly, this Court may properly exercise personal jurisdiction over AtriCure.

15. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and/or 1400(b) at least because AtriCure resides in this District, has a regular and established place of business in this District, and has committed acts of infringement in this District.

INTRA DISTRICT ASSIGNMENT

16. This is an intellectual property action to be assigned on a district-wide basis pursuant to Civil Local Rule 3-2(c).

THE ASSERTED PATENTS

17. On December 26, 2000, the United States Patent and Trademark Office ("USPTO") duly issued United States Patent No. 6,164,283 ("the '283 Patent"), entitled "DEVICE AND METHOD FOR FORMING A CIRCUMFERENTIAL BLOCK IN A PULMONARY VEIN."

The Regents owns by assignment all rights, title and interest in the '283 Patent. A true and correct copy of the '283 Patent is attached hereto as Exhibit 1.

18. On January 7, 2003, the USPTO duly issued United States Patent No. 6,502,576 ("the '576 Patent"), entitled "DEVICE AND METHOD FOR FORMING A CIRCUMFERENTIAL BLOCK IN A PULMONARY VEIN." The Regents owns by assignment all rights, title and interest in the '576 Patent. A true and correct copy of the '576 Patent is attached hereto as Exhibit 2.

19. The '283 and '576 Patents are referred to collectively as the "Asserted Patents."

BACKGROUND OF ATRIAL FIBRILLATION

20. Atrial fibrillation is a type of cardiac arrhythmia that causes an abnormally fast and irregular heart rate. In patients with normal sinus rhythm, the heart is electrically excited to beat in a synchronous, patterned fashion. In patients with a cardiac arrhythmia, however, abnormal regions of cardiac tissue emit erratic electrical signals, disrupting the synchronous beating cycle associated with normally conductive tissue in healthy patients.

21. Atrial fibrillation occurs in the upper chambers of the heart (*i.e.*, atria). In healthy individuals, the heart's atrial and ventricular chambers (*i.e.*, the lower chambers of the heart) contract in a coordinated fashion, with a normal heart rhythm between 60 and 100 beats per minute.

22. In patients with AFib, however, the atrial chambers receive such fast and erratic electrical stimulation that they can only quiver and are unable to actively pump blood from the atria to the ventricles. During AFib, the two atria of the heart "beat" between 350 and 600 times per minute. When this occurs, the atrioventricular node, a part of the electrical pathway between the atria and the ventricles, becomes overloaded with electrical impulses trying to get to the ventricles. As a result, the normal coordination between the atria and ventricles is lost, ventricles develop an irregular heart rhythm, and pumping efficacy is decreased.

23. As a result of blood not being pumped effectively to the ventricles, blood can pool in the atria, posing a serious health risk. The pooling of blood can lead to coagulation and clotting. Strokes occur when a blood clot travels from the atrium, through the arterial system, to

the brain. People with AFib are five times more likely to suffer a stroke than patients without AFib, and more than 15% of all strokes occur in patients with AFib. Once AFib is diagnosed, however, treatment can reduce the risk of stroke.

24. In some patients, the risk of stroke may be reduced with blood thinners to prevent the blood from clotting, and with anti-arrhythmic drugs to restore normal sinus rhythm. These drugs often have serious side effects, such as severe bleeding, dizziness, nausea, bruising, fatigue, lung disease, and ventricular arrhythmias. Further, these drugs often do not prevent further episodes of AFib. If drugs are not effective or well tolerated by a patient, the treatment options include a cardiac ablation procedure, the evolution of which is described more fully below.

DR. MICHAEL LESH INVENTS THE PATENTED METHOD TO TREAT ATRIAL FIBRILLATION

25. Early non-pharmacologic approaches to treat atrial fibrillation were surgical, and involved a complex pattern of surgical incisions in both the left and right atria. The resulting scarred tissue was non-conductive and hence had the potential to block the erratic electrical pulses thought to cause AFib.

26. The early surgical efforts were reported as having some success in treating patients, but these open heart surgeries were highly invasive with the heart stopped, the chest opened, and the patient placed on a heart-lung machine. They also required a long recovery period, tended to render the left atrium non-functional, and had a high risk of death.

27. In parallel with the developments of the surgical procedures described above, doctors began to use catheters to ablate cardiac tissue to treat a variety of cardiac arrhythmias. Catheter ablation is a much less invasive procedure than surgery and is performed by cardiac electrophysiologists ("EPs") in a catheterization lab. EPs are board-certified cardiologists with additional training in treating cardiac arrhythmias. In a catheter ablation procedure, the EP inserts multiple specialized catheters into the patient's veins and arteries. The EP generally guides the catheters into the right atrium of the patient's heart. For procedures involving the left atrium, the EP uses a special catheter to puncture the intra-atrial septum (*i.e.*, the wall separating the left and the right atria) to access the patient's left atrium, where the desired tissue can be ablated.

28. In the early 1990s, EPs began using catheter ablation in an attempt to treat AFib by mimicking the surgical procedures described above. These catheter procedures typically involved the creation of linear patterns of non-conductive tissue from the inside wall of the heart with a goal to create lesions that were transmural (*i.e.*, through the wall from inside to out). In addition, the lesions needed to be continuous (or nearly so) with no gaps. Because they took many hours to complete, these procedures were very stressful for patients and resulted in safety complications such as perforations of the atrium and excessive radiation exposure.

29. In the mid-1990s, research established that approximately 90% of the erratic electrical pulses causing AFib originated somewhere in the pulmonary veins. Thereafter, treating EPs attempted to cure AFib by locating and ablating the point or points (focus or foci) of origination of the erratic electrical signals within the pulmonary veins.

30. These procedures were of limited success because the exact locations of the originating foci are difficult to identify. In addition, there are often multiple originating foci within each pulmonary vein, causing this methodology to be extremely time-consuming. The procedure also posed safety concerns, the most serious of which was stenosis of the pulmonary veins due to excessive scarring. This stenosis blocked oxygen transmission in the blood, and could lead to serious lung problems and even death.

31. Dr. Lesh invented the solution to this life threatening problem. The Patented Method is directed to forming circumferential conduction blocks at locations where the pulmonary veins extend from a patient's left atrium. The resulting circumferential conduction blocks prevent electrical pulses that originate from within or near the pulmonary veins from entering the left atrium and causing AFib. This allows treatment of AFib without having to identify, locate, or ablate the triggering foci within each pulmonary vein. At the same time, it reduces risk of complications posed by previously-employed methods of treatment.

32. Beginning in July 1997, Dr. Lesh filed several related patent applications disclosing and covering the Patented Method. The first of these patents was filed on July 3, 1997, and issued on January 11, 2000, as U.S. Patent No. 6,012,457 ("the '457 Patent") entitled "DEVICE AND METHOD FOR FORMING A CIRCUMFERENTIAL BLOCK IN A

PULMONARY VEIN." The Regents owns by assignment all rights, title and interest in the '457 Patent. A true and correct copy of the '457 Patent is attached hereto as Exhibit 3.

33. The Asserted Patents claim direct priority from the '457 Patent. More specifically, the '576 Patent is a continuation and the '283 Patent is a continuation-in-part of the '457 Patent.

34. The Asserted Patents disclose and claim the Patented Method, as demonstrated in representative claims 1 and 25 of the '283 Patent, and claim 1 of the '576 Patent:

Claim 1 of the '283 Patent

> A method for treating atrial arrhythmia in a patient, comprising:
>
> forming a circumferential conduction block in a circumferential region of tissue at a location where a pulmonary vein extends from an atrium in the patient,
>
> wherein the circumferential conduction block formed is continuous along the circumferential region of tissue, and
>
> wherein the circumferential conduction block is formed without contacting the tissue with an ablative fluid medium.

Claim 25 of the '283 Patent

> A method for treating atrial arrhythmia in a left atrium which includes a left posterior atrial wall having a plurality of pulmonary vein ostia, comprising:
>
> forming a conduction block around a first ostium of the plurality of pulmonary vein ostia from a portion of the left posterior atrial wall which includes at least one of the other pulmonary vein ostia.

Claim 1 of the '576 Patent

> A method for treating atrial arrhythmia in a heart of a patient, wherein the patient includes a plurality of pulmonary veins and each pulmonary vein extends distally along a lumenal axis from a location in an atrium of the heart, the method comprising:
>
> providing a medical device assembly having a distal end portion with an ablation element;
>
> positioning the ablation element at one of the locations where one of the pulmonary veins extends from the atrium, wherein the one location is along either a funneling region of a pulmonary vein ostium of the one pulmonary vein or along a region of the one pulmonary vein comprising cardiac tissue upstream from the

pulmonary vein ostium; and

using said ablation element to ablate a region of tissue that has a continuous circumferential pattern which extends about the lumenal axis of the one pulmonary vein without substantially repositioning the distal end portion.

35. The Patented Method, as disclosed and claimed in the Asserted Patents, is performed using a variety of devices in either a surgical procedure or a less-invasive catheterization procedure. The Patented Method has been adopted by surgeons and surgical devices companies, such as AtriCure, as well as by EPs and electrophysiology device companies.

ATRICURE'S KNOWLEDGE OF THE PATENTED METHOD AND ASSERTED PATENTS

36. By the early 2000s, the Patented Method as claimed in the Asserted Patents had become recognized as the most effective means of treating atrial fibrillation and was the essential element of all non-pharmacological ablation procedures used to treat AFib. In fact, all doctors in the United States that perform surgical or catheter ablation procedures to treat AFib infringe the Asserted Patents, including at least representative claims 1 and 25 of the '283 Patent, and claim 1 of the '576 Patent.

37. AtriCure claims to be one of the market leaders in the surgical treatment of AFib. AtriCure has performed extensive market research on the procedures and equipment used to treat AFib. AtriCure was at all relevant times aware of the Asserted Patents and knew that the Patented Method was the universally-adopted procedure for treating AFib. Indeed, by no later than 2008, AtriCure was sponsoring medical symposia at which leading cardiothoracic surgeons ("Surgeons") were taught to perform the Patented Method using AtriCure Devices.

38. The Regents' Patents, and in particular the Asserted Patents, are well known in the industry, as evidenced by the fact that they are widely cited in patent applications filed by AtriCure and numerous other medical device companies. According to the USPTO's database, the '457 Patent has been cited as relevant prior art in more than 460 patents and patent applications published before 2013. The asserted '283 Patent has been cited as relevant prior art in more than 350 published U.S. patents, and the asserted '576 Patent has been cited as relevant

prior art in more than 100 published U.S. patents.

39. According to the USPTO's database, AtriCure cited the '457 Patent in at least 25 patent applications. As the '283 and '576 Patents are a continuation-in-part and a continuation of the '457 Patent, they contain the same disclosure as the '457 Patent cited by AtriCure in its patent applications. AtriCure also applied for and prosecuted at least three U.S. patent applications which have resulted in issued patents or published patent applications that cite the '283 Patent as prior art. Thus, AtriCure maintains a thorough knowledge of all relevant facts, technologies, inventions, published research, and other developments relating to the Patented Method.

40. AtriCure also specifically discussed the Patented Method in its patent applications. For example, as set forth in the following excerpt from AtriCure's own U.S. Patent No. 8,057,471, AtriCure specifically referenced and explained the universal use of the Patented Method, explaining that the method is designed to:

> "provide a barrier to electrical signals that may otherwise be communicated across the ablated tissue. By way of example only, such a barrier may provide a form of treating atrial fibrillation or other conditions. For instance, **where atrial fibrillation is caused by aberrant or erratic electrical signals coming from one or more pulmonary veins to one or both atria of the heart, an ablation may be provided as a barrier between such veins and atria. In other words, one or more ablations may serve to electrically isolate one or more pulmonary veins from the atria**. By preventing or substantially preventing aberrant or erratic electrical signals coming from one or more pulmonary veins from reaching the atria, a more desirable sinus rhythm may be maintained."
> (3:53-65 (emphasis added)).

41. The Regents also provided AtriCure additional notice of the Asserted Patents. On February 1, 2016, The Regents advised AtriCure in writing that AtriCure Devices were being marketed and sold to Surgeons for use in practicing the Patented Method as claimed in the Asserted Patents. The Regents' letter (attached hereto as Exhibit 4), specifically identified the Asserted Patents and explained that they cover the Patented Method, which "involve[s] the use of various energy sources . . . to ablate heart tissue in a circumferential pattern around the pulmonary vein, disrupting the erratic electric pulses that cause atrial fibrillation."

42. Accordingly, AtriCure had actual knowledge of the Asserted Patents and that the

Asserted Patents cover the Patented Method at all relevant times.

ATRICURE MAKES, PROMOTES AND SELLS A WIDE RANGE OF SURGICAL DEVICES THAT DOCTORS USE TO PERFORM THE PATENTED METHOD

43. During the relevant time period, AtriCure has marketed and sold multiple AtriCure Devices used by Surgeons in violation of the Asserted Patents. At all relevant times, AtriCure was aware that Surgeons used AtriCure Devices to treat AFib and to perform the Patented Method.

44. AtriCure operates primarily in the United States and Europe. AtriCure reports that it employs approximately 500 people worldwide. AtriCure's sole business is selling devices dedicated to treating AFib. AtriCure's reported revenue for U.S. sales of AFib treatment devices and equipment has ranged from $60 million in 2010 to $102 million in 2015.

45. When promoting its AtriCure Devices for treatment of AFib, AtriCure understands, and the relevant medical community understands, that it is promoting the AtriCure Devices to be used specifically to perform the Patented Method. During the relevant time period, AtriCure has marketed and sold a number of ablation catheters specifically for use by Surgeons in performing the Patented Method. These include, but are not limited to, the following:

- **RF Ablation Clamps**, including but not limited to: Isolator Synergy Ablation Clamps (OLL2 / OSL2), Isolator Synergy Clamps (EML2 / EMR2), Isolator Synergy Access Clamp (EMT1).
- **Other Ablation Devices and Probes**, including but not limited to: Coolrail Linear Pen, Isolator Linear Pen, Isolator Transpolar Pen, AFfirm Bipolar Pacing Probe, CryoICE Cryoablation Probe (CRYO2), CryoICE Cryoablation Probe (CRYO3), CryoFORM Cryoablation Probe, CryoICE Probe for Cryoanalgesia, COBRA Fusion 50 Ablation System, COBRA Fusion 150 Ablation System, Fusion Magnetic Retriever System.
- **Minimally Invasive Devices**, including but not limited to: EPi-Sense Coagulation Device, Subtle Cannula.
- **Other Surgical Devices**, including but not limited to: Lumitip Dissection System,

Hercules Universal Stabilizer Arms, Retractors and Blades, Retractors, Atrial Lift System, Rakes and Valve Assistants, Graspers, Scissors, Needle Holders, LiV Accessories.

- **Sensing Equipment**, including but not limited to: ORLab System, Ablation Sensing Unit and Switch Matrix, Electrosurgical Unit.
- **Ablation Generators**, including but not limited to: RF Generator, CryoICE BOX V6.

46. Numerous AtriCure Devices, including many listed above, are specifically designed for and used by Surgeons only as a material part of performing the Patented Method. With knowledge of the Asserted Patents, AtriCure has knowingly promoted such AtriCure Devices as specifically designed for the purpose of being used by Surgeons to perform the Patented Method. These particular AtriCure Devices, which have no substantial non-infringing uses include, but are not limited to, the following:

- **RF Ablation Clamps**, including but not limited to: Isolator Synergy Ablation Clamps (OLL2 / OSL2), Isolator Synergy Clamps (EML2 / EMR2), Isolator Synergy Access Clamp (EMT1).

47. Not only is AtriCure aware that Surgeons use AtriCure Devices to perform the Patented Method—which is covered by the Asserted Patents—but it specifically intends for Surgeons to continue that use as it is critical to AtriCure's business. Indeed, AtriCure has stated that its future revenue depends on increasing acceptance by the medical community of the surgical treatment of AFib and the existence, effectiveness and, in particular, the safety of AtriCure's products. *See* Excerpts of AtriCure's 2013 Annual Report attached hereto as Exhibit 5, at 16.

48. At all relevant times, Surgeons have used AtriCure Devices to perform the Patented Method in the United States in violation of the Asserted Patents. AtriCure has at all relevant times promoted, marketed, and advertised the AtriCure Devices to be used by Surgeons to perform the Patented Method. AtriCure was aware of and intended Surgeons to use the AtriCure Devices to specifically perform the Patented Method in violation of the Asserted Patents.

ATRICURE'S INFRINGEMENT OF THE ASSERTED PATENTS

49. AtriCure at all relevant times has induced and contributed to the infringement of the Asserted Patents. With actual knowledge of the Asserted Patents, AtriCure actively encouraged Surgeons to use AtriCure Devices to perform the Patented Method with specific intent to infringe the Asserted Patents. With actual knowledge of the Asserted Patents, AtriCure sold AtriCure Devices that have no substantial non-infringing uses, contributing to the infringement of the Asserted Patents by Surgeons.

AtriCure's Synergy Ablation System Is Approved by The FDA for Treatment of AFib to Perform the Patented Method

50. AtriCure makes and sells AtriCure Devices specifically for surgically treating AFib by performing an FDA-approved method that includes circumferential ablation lesions that isolate the pulmonary veins, *i.e.*, the Patented Method. AtriCure's FDA-approved label specifically teaches use of AtriCure Devices according to the Patented Method.

51. AtriCure first sought and obtained FDA approval in 2001 to market certain AtriCure Devices, specifically the Synergy Ablation System (which includes the Isolator Synergy Ablation Clamps, Ablation Sensing Units and Switch Matrixes), under the FDA-approved indication that the System, along with radiofrequency and cryoenergy generators, "is intended to ablate soft tissue during general surgery using radiofrequency energy." As explained below, in December 2011, the FDA updated the approved indication to specify the Synergy Ablation System's intended and actual use as a tool to ablate cardiac tissue to treat AFib using the Patented Method.

52. Prior to 2010, AtriCure began actively marketing the Synergy Ablation System to Surgeons to perform a specific pattern of cardiac ablations that requires, as its most important step, pulmonary vein isolation (PVI). In other words, AtriCure routinely promotes and teaches Surgeons to practice the Patented Method using its Synergy Ablation System.

53. In late December 2010, after being sued by the United States Department of Justice for violations of the False Claim Act for *inter alia* promoting the non-FDA-approved (or "off-label") use of AtriCure Devices to perform the Patented Method, AtriCure submitted a

Premarket Approval Application ("PMA") to the FDA seeking to expand the devices' pre-existing indication to include the express approval to market the Synergy Ablation System to Surgeons for purposes of performing the Patented Method. As stated in the application, the goal was "to have an updated label specifically for treatment of atrial fibrillation," so as to "enable AtriCure to conduct training programs to ensure surgeons learn the optimal surgical technique with the AtriCure Synergy Ablation System." Exhibit 6 at 9. This surgical technique includes the Patented Method. A copy of relevant excerpts of the AtriCure Synergy Ablation System Panel Pack Executive Summary is attached as Exhibit 6. (*See especially* 7-9.)

54. On December 14, 2011, the FDA granted AtriCure's application and approved the Synergy Ablation System (PMA P100046), with an indication to "ablate cardiac tissue for the treatment of persistent atrial fibrillation" in patients who are undergoing open concomitant coronary artery bypass and/or valve replacement and repair. The FDA-approved label, relevant excerpts of which are attached as Exhibit 7, includes specific instructions for using the Synergy Ablation System to perform the Patented Method. The image reproduced below, from AtriCure's FDA-approved marketing label, specifically illustrates—and promotes—using AtriCure Devices to perform the Patented Method by creating the circumferential PVI lesions (highlighted in yellow):

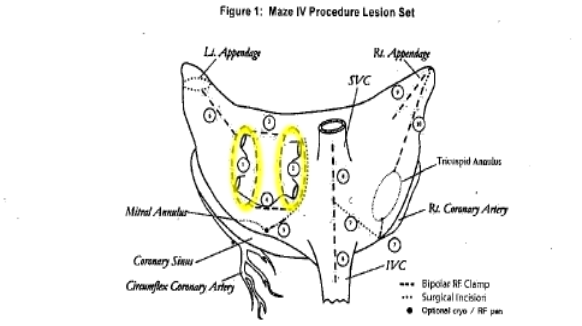

Exhibit 7 at 8.

55. AtriCure advertises on its website, attached as Exhibit 8, that "[t]he Isolator Synergy Ablation Clamp is the FIRST and ONLY surgical ablation device offered with FDA approval for the treatment of Atrial Fibrillation." AtriCure specifically intends for Surgeons to

use the AtriCure Devices to perform the Patented Method to treat AFib, in violation of the Asserted Patents.

56. As AtriCure has told its investors "[r]egardless of the duration or type of Afib, **surgeons will create lesions in the heart tissue surrounding the pulmonary veins to create an electrical barrier between the pulmonary veins and the atrium**, or upper chambers of the heart." Exhibit 5 at 13 (emphasis added).

AtriCure's Training of Surgeons

57. At all relevant times, AtriCure has also offered courses teaching Surgeons to use its AtriCure Devices to perform the Patented Method. By way of example, AtriCure has offered and continues to offer an "AtriCure Maze IV Surgical Training Course." AtriCure developed, and promoted, the training course in partnership with recognized key opinion leaders in AFib surgery. AtriCure's brochure advertising this program, a true and correct copy of which is attached hereto as Exhibit 9, depicts and teaches the use of circumferential PVI ablation lesions, according to the Patented Method of the Asserted Patents (highlighted in yellow).

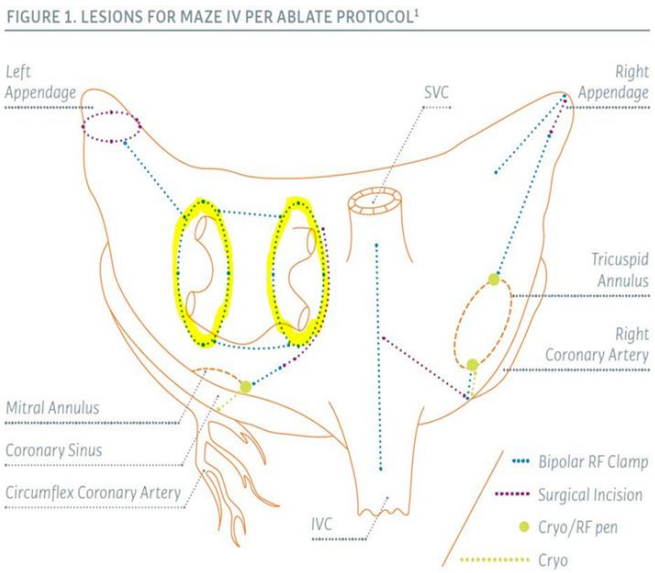

Exhibit 9 at 4.

58. AtriCure also employs a direct sales force, currently consisting of approximately 100-125 highly trained sales team employees, supporting approximately 53 sales territories in the

United States, teaching the use of and selling AtriCure Devices for treating AFib to medical centers throughout the United States. AtriCure selects these sales employees based on their expertise and reputation in the medical device industry and their knowledge of the requisite cardiac surgery procedures and technologies for performing the Patented Method. AtriCure instructs and expects its large, medically skilled sales force to meet with doctors at leading institutions to provide education specifically "on the use of the Synergy System to treat certain AFib patients." Exhibit 5 at 13; *see also id*. at 3. AtriCure reported that, as of 2013, over 1,200 physicians had been trained to perform the Patented Method. *Id.* at 3.

59. AtriCure's teaching materials, including its brochure for the "AtriCure Maze IV Surgical Training Course" attached as Exhibit 9 and illustrated below, present an AtriCure sales representative demonstrating how the Isolator Synergy Ablation Clamps are used to create these circumferential PVI ablation lesions:

Exhibit 9 at 1.

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AtriCure's Other Marketing Activities

60. AtriCure has expressly recognized that its business model depends on the increasing acceptance by the medical community of AtriCure Devices as a standard surgical treatment of AFib during open-heart surgical procedures, and also as a sole-therapy minimally invasive procedure.

61. To promote this acceptance, AtriCure creates and distributes promotional materials that further describe and promote the use of AtriCure Devices to perform the Patented Method. As just one example, the below image from the Isolator Synergy Ablation System brochure, a true and correct copy which is attached hereto as Exhibit 10, specifically demonstrates the use of AtriCure's Synergy Ablation System to perform circumferential PVI, including creation of circumferential ablation lesions around the PV ostia, identified as "Right antral PV isolation (right PVI)," and "left antral PV isolation (left PVI)." *Id.* at 5.

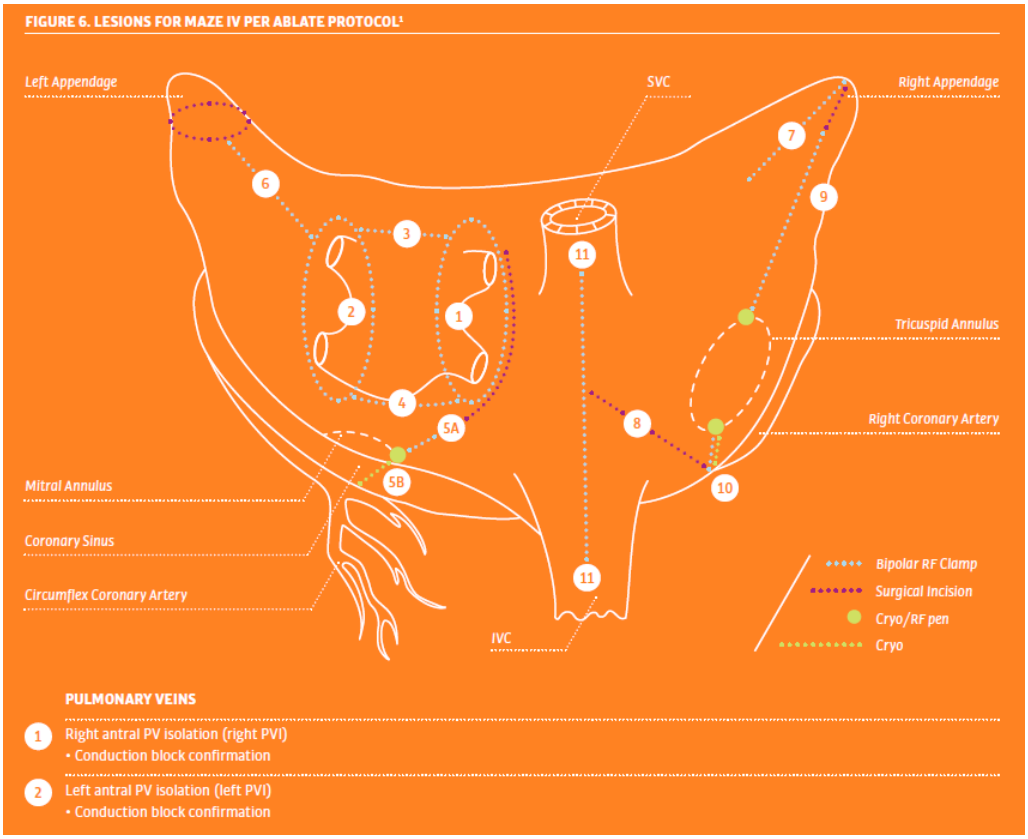

Exhibit 10 at 5.

62. To further promote the use of AtriCure Devices in performing the Patented Method, AtriCure has explained in its annual reports that it also engages in activities such as: investing in clinical trials to validate and promote the use of AtriCure Devices in performing the Patented Method; providing "educational grants to institutions" to teach the use of AtriCure Devices "as an AFib treatment"; sponsoring publication of peer-reviewed articles teaching the use of AtriCure Devices to perform the Patented Method; and forming advisory boards and other "consulting relationships" with cardiothoracic surgeons and other "key opinion leaders" in cardiac surgery and other specialties, to oversee AtriCure's surgical training programs and to further promote the use of AtriCure Devices to perform the Patented Method. Exhibit 5 at 14.

63. To further market and promote the sale and use of AtriCure Devices, with the specific intent that the Devices are used by Surgeons to perform the Patented Method, AtriCure further explains in its annual reports that it has done and continues to do the following:

- Funds the publication of articles on the use of AtriCure Devices to perform the Patented Method;
- Provides grants or other support to renowned Surgeons, medical teaching institutions and other "thought leaders," to teach the use of AtriCure Devices to perform the Patented Method; and
- Engages in its own extensive training of Surgeons on the use of AtriCure Devices to perform the Patented Method. *Id.*

64. Upon information and belief, AtriCure promoted and marketed the AtriCure Devices to perform the Patented Method throughout the 2000s. The AtriCure Devices were on the market in 2001, but were not yet approved for marketing for the treatment of AFib until 2011. As the AtriCure Devices were designed to perform the Patented Method, AtriCure marketed the AtriCure Devices for performing the Patented Method. Indeed, AtriCure was sued for marketing off-label use in a False Claims Act qui tam case in July 2009, which the Department of Justice eventually prosecuted. In 2010, AtriCure agreed to pay $3.8 million to resolve the False Claims Act suit based on its marketing of the AtriCure Devices to be used for the Patented Method.

65. AtriCure's marketing activities alleged herein were performed for the commercial

purpose of selling AtriCure Devices, and were not reasonably related to the development and submission of information necessary to obtain regulatory approval from the FDA, nor were they directed to the collection of information or data necessary for filing an application with the FDA for approval to market any AtriCure Device. The AtriCure Devices promoted by AtriCure, as alleged above, were approved and on the United States market, and being used to perform the Patented Method prior to AtriCure engaging in the marketing and promotional conduct alleged herein.

66. On February 1, 2016, The Regents wrote to AtriCure and advised it of The Regents' concern that AtriCure's products were being marketed and sold to doctors for use in practicing the Patented Method. AtriCure has ignored, and never even acknowledged receipt of, The Regents' letter. AtriCure has not in any way changed its marketing or promotional practices so as to stop its infringement of the Asserted Patents.

COUNT I: INFRINGEMENT OF THE '283 PATENT

67. Plaintiff re-alleges here all of the allegations set forth in paragraphs 1-66 above.

68. At all relevant times, AtriCure had knowledge of the '283 Patent and the Patented Method.

69. AtriCure induces others to infringe and/or contributorily infringes one or more claims of the '283 Patent, either literally or under the doctrine of equivalents.

70. Claim 25 of the '283 Patent recites:

> A method for treating atrial arrhythmia in a left atrium which includes a left posterior atrial wall having a plurality of pulmonary vein ostia, comprising:
>
> forming a conduction block around a first ostium of the plurality of pulmonary vein ostia from a portion of the left posterior atrial wall which includes at least one of the other pulmonary vein ostia.

71. The use of the AtriCure Devices by Surgeons to perform the Patented Method on patients with AFib satisfies each and every limitation of claim 25 of the '283 Patent. For example, when Surgeons use AtriCure's Synergy Ablation System including the Isolator Synergy Ablation Clamps to treat AFib, Surgeons use the clamp to form a conduction block around a pulmonary

vein ostia from a portion of the left atrial wall, which includes at least one other pulmonary vein ostia. The Surgeons' use of AtriCure's Synergy Ablation System, and related devices, to perform the Patented Method, as described above, satisfies at least Claim 25 of the '283 Patent. At all relevant times, AtriCure knowingly encouraged and intended Surgeons to use AtriCure Devices to perform the Patented Method on patients who have been diagnosed with AFib as described above, in violation of claim 25.

72. Upon information and belief, both by manufacturing AtriCure Devices to be used in a manner that AtriCure knows infringes the '283 Patent, and by encouraging Surgeons to use the AtriCure Devices in a manner that AtriCure knows infringes the '283 Patent, AtriCure is inducing infringement of the '283 Patent by Surgeons in violation of 35 U.S.C. § 271(b). For example, AtriCure's marketing and promotional materials tout the use of AtriCure Devices to perform the Patented Method in a manner that falls within the scope of at least claim 25 of the '283 Patent.

73. A subset of AtriCure Devices sold by AtriCure, as set forth in paragraph 46, are material to performing the Patented Method, according to claim 25 of the '283 Patent.

74. This subset of AtriCure Devices is not a staple article or commodity of commerce, nor suitable for substantial non-infringing uses. Moreover, by its actual knowledge of the '283 Patent, AtriCure knew that a subset of the AtriCure Devices are especially made or especially adapted for use in a manner that infringes the '283 Patent. Accordingly, AtriCure's sale of the subset of AtriCure Devices set forth in paragraph 46 contributes to the infringement of at least claim 25 of the '283 Patent by Surgeons in violation of 35 U.S.C. § 271(c).

75. AtriCure has profited and will continue to profit from its infringement of the '283 Patent.

76. AtriCure's infringement of the '283 patent has caused and will continue to cause The Regents substantial monetary harm, for which The Regents is entitled to receive compensatory damages in an amount to be determined at trial, but in no event less than a reasonable royalty.

77. Further, AtriCure's infringement of the '283 Patent has been willful, deliberate,

and with full knowledge that the use of AtriCure Devices infringes the '283 Patent, justifying an increase in the damages to be awarded to The Regents up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

78. AtriCure's willful infringement of the '283 Patent, among other actions, renders this an exceptional case, justifying the award to The Regents of its reasonable attorney fees, in accordance with 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE '576 PATENT

79. Plaintiff re-alleges here all of the allegations set forth in paragraphs 1-66 above.

80. At all relevant times, AtriCure had knowledge of the '576 Patent and the Patented Method.

81. AtriCure induces others to infringe and/or contributorily infringes one or more claims of the '576 Patent, either literally or under the doctrine of equivalents.

82. Claim 1 of the '576 Patent recites:

> A method for treating atrial arrhythmia in a heart of a patient, wherein the patient includes a plurality of pulmonary veins and each pulmonary vein extends distally along a lumenal axis from a location in an atrium of the heart, the method comprising:
>
> providing a medical device assembly having a distal end portion with an ablation element;
>
> positioning the ablation element at one of the locations where one of the pulmonary veins extends from the atrium, wherein the one location is along either a funneling region of a pulmonary vein ostium of the one pulmonary vein or along a region of the one pulmonary vein comprising cardiac tissue upstream from the pulmonary vein ostium; and
>
> using said ablation element to ablate a region of tissue that has a continuous circumferential pattern which extends about the lumenal axis of the one pulmonary vein without substantially repositioning the distal end portion.

83. The use of AtriCure Devices by Surgeons to perform the Patented Method on patients with AFib satisfies each and every limitation of claim 1 of the '576 Patent. For example, when Surgeons use AtriCure's Synergy Ablation System to treat AFib including the Isolator

Synergy Ablation Clamps and other devices, the Isolator Synergy Ablation Claims have an ablation element at their distal ends. Surgeons position the ablation element of the clamps at a location where one of the pulmonary veins extends from the atrium at a funneling region of a pulmonary vein ostium, to ablate a region of tissue with a continuous circumferential pattern, which extends about the lumenal axis of one pulmonary vein, without substantially repositioning the distal end portion. The Surgeons' use of AtriCure's Synergy Ablation System, and related AtriCure Devices, to perform the Patented Method, as described above, satisfies at least Claim 1 of the '576 Patent.

84. At all relevant times, AtriCure knowingly encouraged and intended Surgeons to use AtriCure Devices to perform the Patented Method on patients who have been diagnosed with AFib as described above, in violation of claim 1.

85. Upon information and belief, both by manufacturing AtriCure Devices to be used in a manner that AtriCure knows infringes the '576 Patent, and by encouraging Surgeons to use the AtriCure Devices in a manner that AtriCure knows infringes the '576 Patent, AtriCure is inducing infringement of the '576 Patent by Surgeons in violation of 35 U.S.C. § 271(b). For example, AtriCure's marketing and promotion materials tout the use of AtriCure Devices to perform the Patented Method in a manner that falls within the scope of at least claim 1 of the '576 Patent.

86. A subset of AtriCure Devices sold by AtriCure, as set forth in paragraph 46, are material to performing the Patented Method, according to claim 1 of the '576 Patent.

87. This subset of AtriCure Devices is not a staple article or commodity of commerce, nor suitable for substantial non-infringing uses. Moreover, by its actual knowledge of the '576 Patent, AtriCure knew that a subset of the AtriCure Devices are especially made or especially adapted for use in a manner than infringes the '576 Patent. Accordingly, AtriCure's sale of the subset of AtriCure Devices set forth in paragraph 46 contributes to the infringement of at least Claim 1 of the '576 Patent by Surgeons in violation of 35 U.S.C. § 271(c).

88. AtriCure has profited and will continue to profit from its infringement of the '576 Patent.

89. AtriCure's infringement of the '576 Patent has caused and will continue to cause The Regents substantial monetary harm, for which The Regents is entitled to receive compensatory damages in an amount to be determined at trial, but in no event less than a reasonable royalty.

90. Further, AtriCure's infringement of the '576 Patent has been willful, deliberate, and with full knowledge that the use of AtriCure Devices infringes the '576 Patent, justifying an increase in the damages to be awarded to The Regents up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

91. AtriCure's willful infringement of the '576 Patent, among other actions, renders this an exceptional case, justifying the award to The Regents of its reasonable attorney fees, in accordance with 35 U.S.C. § 285.

PRAYER FOR RELIEF

Wherefore, The Regents of the University of California respectfully requests that the Court enter a judgment as follows:

A. That AtriCure has infringed the Asserted Patents;

B. Awarding The Regents damages, including enhanced damages, pursuant to 35 U.S.C. § 284, for AtriCure's infringement of the Asserted Patents, in an amount to be determined at trial, but in no event less than a reasonable royalty;

C. Awarding The Regents pre-judgment and post-judgment interest to compensate The Regents for the damages it has sustained;

D. Awarding The Regents all of its costs and disbursements incurred in bringing this action;

E. Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding The Regents' its reasonable attorney fees, costs, and expenses; and

F. Awarding The Regents any further relief the Court deems just and proper.

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Respectfully submitted,

DATED: November 8, 2016

CROWELL & MORING LLP

By: */s/ Mark T. Jansen*
Mark T. Jansen
Kathryn L. Clune
Pilar R. Stillwater
Ali H.K. Tehrani
Galen P. Sallomi
Attorneys for Plaintiff
THE REGENTS OF THE
UNIVERSITY OF CALIFORNIA

DEMAND FOR JURY TRIAL

The Regents of the University of California hereby requests a trial by a jury on all issues so triable.

Respectfully submitted,

DATED: November 8, 2016

CROWELL & MORING LLP

By: */s/ Mark T. Jansen*
Mark T. Jansen
Kathryn L. Clune
Pilar R. Stillwater
Ali H.K. Tehrani
Galen P. Sallomi
Attorneys for Plaintiff
THE REGENTS OF THE
UNIVERSITY OF CALIFORNIA